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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOO, JULIAN W

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,344

Applicant(s)

MODESITT ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26, 27, 48-78 and 80-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 92 and 93 is/are allowed.
- 6) ☒ Claim(s) 26, 48, 49, 64, 65, 69, 70, 72, 73, 85, 86, 89 is/are rejected.
- 7) ☒ Claim(s) 27, 50-63, 66-68, 71, 74-78, 80-84, 87, 88, 90 and 91 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 86 is objected to because of the informality, which can be corrected as follows: In line 2, insert --with-- after "needle." Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 26, 48, 49, 64, 65, and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (5,527,322). With respect to claims 26, 48, 49, 64, and 65, Klein et al. disclose, in figures 1 and 8-13 and in col. 11, lines 51-56, a method for suturing a puncture (P) or aperture of a blood vessel (BV), where the method includes inserting a device or the distal end of a probe (14) into a blood vessel at the aperture, advancing a first end of a suture (62) or suture element from the probe through the vessel wall adjacent to the aperture and into the vessel; extending the suture element across the aperture; withdrawing the first end of the suture from the vessel at a vessel wall position opposed from the position of the aforementioned suture advancement and through a bight (see fig. 13) of the suture to form a loop while the bight is pre-arranged on the device (see col. 11, lines 51-56, where a knot is tied (i.e., a bight is formed) prior

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to removal of the device from the vessel); and tensioning the first and second ends of the suture adjacent the bight to form a knot (see element K in fig. 13, specifically).

4. Claims 69, 70, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (5,417,699). Klein et al. disclose, in figures 2 and 7-12, a device (10) with a body (22), at least one suture element (30) held on the body, and means for passing the suture element through a vessel wall adjacent an aperture in the vessel wall or at least one needle (20) on the body. The suture element, as seen in figures 10-12, spans across the aperture and is positioned to define a knot (72) between opposed portions of the suture element.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 85 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (4,950,285). Wilk discloses the invention substantially as claimed. Wilk

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discloses, in figures 2 and 9A-9D and in col. 8, lines 49-54, methods for suturing blood vessel walls (for "controlling bleeding vessels" and "anastomoses") using a device (210) with a suture (226) having a bight (224) and a needle (232) with a distal tip. Wilk, however, does not disclose suturing a puncture in a blood vessel. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply Wilk's device for the suturing of a puncture. Wilk's device can be dimensioned to a size appropriate for closing a puncture or a small incision in a blood vessel, and for example, control bleeding from the wound.

Allowable Subject Matter

7. Claims 92 and 93 are allowed.
8. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method for suturing a puncture in a blood vessel wall, where, inter alia, a first needle carrying a suture element with a bight is advanced through a vessel wall, where an end of the suture element and a second needle are coupled to a connection element, and where the second needle, the connection element, and the end of the suture element are pulled through the bight to form a knot.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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9. Claims 27, 50-63, 66-68, 71, 74-84, 87, 88, 90, and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method for suturing a puncture or aperture in a wall of a blood vessel, where the method includes inserting a device, probe, or shaft through the puncture, moving a suture through the vessel wall on opposed positions adjacent the puncture or aperture, and releasably attaching a bight of the suture to the probe or shaft before its insertion through a puncture; where first and second needles are advanceable with the shaft, and where the suture element has a loop formation on a portion thereof, so that the device passes another portion of the suture element through the loop formation. The prior art of record also does not disclose a device for closing an aperture in the vessel wall, where an elongate foot is deployed from the device within the vessel; where at least two suture elements are held on the device body along with means for passing each element through the vessel wall; and where a needle is arranged to pass a portion of the suture element device through loop formation on another portion of the suture element.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. With respect to arguments regarding the rejection of claims based on Klein et al. (5,527,322 and 5,417,699), see the rejections above. In short, Klein et al. do disclose each and every element of the claims, where a bight is broadly defined as a loop of suture or a bent portion of suture, where knot-forming entails inserting an end of suture through a bight, and where tying of sutures inherently includes the formation of at least one bight.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Granger et al. (5,259,846) and Yoon (5,643,295) teach devices each with a needle, a suture, and a bight in the suture.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.



Julian W. Woo
Primary Examiner

November 6, 2003